

**REMARKS**

Claims 39-53 and 67-74 are currently pending in the application. In response to the Notice of Non-Compliant Amendment mailed dated August 28, 2009, Applicant responds by resubmitting it's Amendment and Request for Continued Examination 37 C.F.R. §1.112, which was filed on August 17, 2009 in response to the Board Decision mailed on June 17, 2009. The Board Decision Appeal 2008-1316 ("the Board Decision") affirmed the Examiner's rejection of claims 39-53 and 67-74 under 35 U.S.C. § 102(e) as anticipated by *Whitcher*. The Board Decision was mail dated June 17, 2009 and the Applicant resubmits herewith a Request for Continued Examination within the two month time period for reply. Applicant submits a submission subsequently recited herein, and respectfully request reconsideration and further examination of the present application under 37 C.F.R. §1.112.

**ARGUMENTS**

A. 35 U.S.C. § 102(e) rejection of pending claims 39-53 and 67-74 as being anticipated by *Whitcher* et al. (U.S. Pub. No. US 2003/0018381).

The pending application is directed towards a method of manufacturing an endoluminal stent. More specifically, the claimed method (as recited in independent claims 39, 47, and 67 of the Application) requires, *inter alia*, the step of vacuum depositing a stent-forming metal onto a substrate under process conditions selected to minimize (or substantially eliminate) formation of chemical and intra- and inter-granular precipitates in the bulk material of the as deposited crystalline film.

The Board Decision stated that *Whitcher* explicitly describes deposition of monocrystalline and nanocrystalline metallic films (Board Decision, FF 15). The term nanocrystalline is undefined in *Whitcher*; however, it is generally understood to simply be nano-scale polycrystalline structures. (See, e.g., Hollister, P., et al., Nanocrystalline Materials, Technology White Papers nr. 4, Cientifica, Oct. 2003, [nanotechweb.org/dl/wp/nanocrystalline\\_materials\\_WP.pdf](http://nanotechweb.org/dl/wp/nanocrystalline_materials_WP.pdf), a copy of which is attached as Exhibit A). The term "monocrystalline" is also undefined in *Whitcher*. However, that term is generally understood to mean "formed of a single crystal-unit, and so all elements have identical crystallographic orientation of c- and a-axes and overgrow as one unit." (See, [www.nhm.ac.uk/hosted\\_sites/ina/terminology/7crystallography.htm](http://www.nhm.ac.uk/hosted_sites/ina/terminology/7crystallography.htm).) Monocrystalline (a/k/a

single crystal) materials as taught by *Whitcher* as drawn filaments and are not, therefore, vacuum deposited onto a cylindrical substrate to form a tubular film structure. And nano-scale crystal structures are desirable to enhance mechanical properties of the medical device, and have nothing to do with precipitates. As such, *Whitcher* does not disclose, expressly or implicitly, that vacuum deposition may be controlled to minimize formation of precipitates in the as-deposited crystalline film.

The Board Decision stated that *Whitcher* describes a vacuum deposition process for controlling the composition, thickness, surface roughness, and microstructure" of the medical devices" and impart "desired compositions, mechanical properties, and geometries" (Board Decision, FF 11, 12). Applicant submits that the concept of controlling aspects of the microstructure of a deposited metal is different from the concept of minimizing precipitates in a deposited metal film. As widely known to those skilled in the metallurgical arts, the term "precipitate"<sup>1</sup> is different from the term "microstructure"<sup>2</sup> and different from the term "impurity"<sup>3</sup>. In the metallurgical arts as they pertain to fabrication of biomaterials, and with particular reference to nickel-titanium shape memory alloys, precipitates are reaction products formed from a solid solution under increased thermal conditions which drive the precipitate from solution, resulting in formation of the reaction products outside the solid solution, *i.e.*, the metal crystalline structure. An excellent monograph on precipitation reactions in nickel-titanium binary shape memory alloy systems is found at Pelton, A.R., et al., Optimisation of processing and properties of medical grade Nitinol Wire, *Min Invas Ther & Allied Techno.*, 2000: 9(1) 107–118, a copy of which is attached as Exhibit B.

Thus, a "precipitate" is not an "impurity." Rather, it is a reaction product from the solid metal solution. Conversely, an "impurity" is not a "precipitate". Indeed, on paragraph 37, *Whitcher* clearly notes that "other impurities, such as oxygen, that may be contained in the elemental ingot may be filtered away from the substrate with this method" [Emphasis added]. Based on Applicant's meticulous reading, there is no description whatsoever in *Whitcher*

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<sup>1</sup> Online website <www.dictionary.com> defines the term precipitate as "a substance precipitated from a solution" and "to separate (a substance) in solid form from a solution, as by means of a reagent."

<sup>2</sup> Online website <www.dictionary.com> defines the term microstructure as "the structure of a metal or alloy as observed, after etching and polishing, under a high degree of magnification."

<sup>3</sup> Online website <www.dictionary.com> defines the term impurity as "the quality or state of being impure."

indicating that the “impurities” described in *Whitcher* and referenced by the Examiner, actually refer to precipitates.

Additionally, the Board Decision stated that no working examples or specific vacuum deposition conditions are described in the Specification (FF8). However, the present application states “[a]s is described in co-pending, commonly assigned, U.S. Patent Application Serial No. 09/443,929, filed November 19, 1999, which is hereby incorporated by reference, heterogeneities are controlled by fabricating the bulk material of the stent to have defined grain sizes, chemical and intra and intergranular precipitates and where the bulk and surface morphology differ, yielding areas or sites along the surface of the stent while maintaining acceptable or optimal protein binding capability. Present Application, page 10, lines 24-30. The U.S. Patent Application Serial No. 09/443,929 has subsequently issued as U.S. Patent No. 6,379,383 (the ‘383 patent’). The ‘383 patent lists several examples of specific vacuum deposition conditions. See e.g. Examples 1-4 of the ‘383 patent. Such vacuum deposition conditions disclosed in the ‘383 patent are remarkably different than *Whitcher*, i.e. substrate temperature between about 300 and 110 degrees and bias voltage between -1000 and +1000 volts for sputtering. The ‘383 patent, col. 7, lines 13-15. *Whitcher* does not teach or disclose such vacuum deposition conditions. As such, the present application supports vacuum deposition conditions to minimize (or substantially eliminate) formation of chemical and intra- and inter-granular precipitates in the bulk material of the as deposited crystalline film, and *Whitcher* fails to anticipate claims 39-53 and 67-74.

Regarding Claim 58, *Whitcher* does not teach or suggest that the nickel-titanium has a composition of between about 51.5 and about 55.0 atomic percent nickel. *Whitcher* only teaches that the nitinol source target includes about 55.9% wt. nickel and the balance essentially titanium. *Whitcher*, Examples 1-5, ¶¶ [0066]-[0074]. As such, Claim 58 is novel in light of *Whitcher*.

Thus, for the reasons stated above, Applicant submits that pending claims 39-53 and 67-74 are distinguished from the prior art cited and of record.

**Summary**

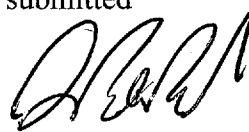
Accordingly, Applicants submit that the pending claims are patentably distinct from and over the art cited and of record. Favorable reconsideration of the rejection of the pending claims is solicited.

Any amendments made during the prosecution of this application are intended solely to expedite prosecution of the application and are not to be interpreted as acknowledgement of the validity of any rejection raised earlier in prosecution, nor as acknowledgement that any citation made against the application is material to the patentability of the application prior to amendment.

No additional fees are believed necessitated by the filing of this Paper. Should any such additional fees be required, the Commissioner is hereby authorized to deduct them from Deposit Account No. 18-2000, of which the undersigned is an authorized signatory.

Should the Examiner believe that there are any outstanding matters capable of resolution by a telephone interview, the Examiner is encouraged to telephone the undersigned attorney of record.

Respectfully submitted



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